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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,319	12/20/2005	Neville J. Anthony	21444YP	9438
<div>210 7590 08/07/2007</div> <div>MERCK AND CO., INC</div> <div>P O BOX 2000</div> <div>RAHWAY, NJ 07065-0907</div>				
EXAMINER				
KEYS, ROSALYND ANN				
ART UNIT		PAPER NUMBER		
1621				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,319

Applicant(s)

ANTHONY ET AL.

Examiner

Rosalynd Keys

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/16/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Claims

1. Claims 1-15 are pending.

Claims 1-15 are rejected.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 16, 2006 has been considered by the examiner.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the R4 groups s-triazolo[1,5-a]pyrimidinyl; thieno[3,2-b]pyridinyl; and imidazo[2,1-b]thiazolyl, as disclosed in lines 7-9 of claim 7, is not described in the specification, with respect to D being C(O)R4 (see page 6, lines 26-30); the limitation "Rd and Re, together with the nitrogen atom to which they are attached", as disclosed in claim 8, is not described in the specification (see page 7, lines 3 and 4); the R4 group thieno[3,2-b]pyridinyl, as disclosed in claim 8, is not described in the specification (see page 7, lines 7-25); the R4 group pyrazolo[1,5-a]pyrimidinyl, as disclosed in lines 5 and 6 of claim 9, is not described in the specification, with respect to D being C(O)NRdR4 (see page 7, line 12); the limitation "Rd and R4 together with the nitrogen atom to which they are attached", as disclosed in claim 9, is not described in the specification with respect to D being C(O)NRdR4 (see page 7, line 15); the R4 group 1,4-dioxanyl, as disclosed in line 6 of claim 10, is not described in the specification (see page 7, lines 7-25); the limitation "Rd and Re, together with the nitrogen atom to which they are attached", as disclosed in claim 11, is not described in the specification (see page 7, lines 27 and 28); and the limitations of claim 12 is not described in the specification.

Claim Objections

4. Claim 9 is objected to because of the following informalities: the word "imidazoly" in line 4 is an incorrect spelling for the word "imidazolyl". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because of the limitation "D is not NHC(O)C1-6alkyl". D is defined in line 9 on page 55. Perhaps the Applicants mean to say: when Rd is H, then D is not COR4 and R4 is not C1-6alkyl.

Claim 5 is further indefinite because page 5, line 29 discloses that Rd and Re together with the nitrogen to which they are attached complete a 4- to 8-membered ring. In claim 5 the presence of nitrogen is not disclosed.

7. Claims 14 and 15 provide for the use of a compound of formula I, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

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results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4, 6, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajagopalan et al. (Proceedings-Indian Academy of Sciences, Section A, 1942, 15A, pp. 432-436).

Rajagopalan et al. teach compounds having the claimed formula I, wherein A is O, D is COR₄; R₄ is a C₁ alkyl (methyl); each occurrence of X, Y, and Z are ring carbon atoms; R_{1a}, R_{1b}, R_{2a}, R_{3a} and R_d are H (see entire disclosure, in particular page 433).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Aries (FR 2 290 431).

Aries teach compounds having the claimed formula I (see entire disclosure, in particular example 2 and claim 4 of the French patent and the attached English abstract). The compounds are recrystallized from aqueous ethanol, which is a pharmaceutically acceptable carrier (see examples 1 and 2).

12. Claims 1, 4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloetzel et al. (Journal of Medicinal & Pharmaceutical Chemistry, 1959, Vol. 1, No. 3, pp. 197-211).

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Kloetzel et al. teach a compounds having the claimed formula I (see entire disclosure, in particular pages 198 and 204). The compounds are crystallized from ethanol, which is a pharmaceutically acceptable carrier (see the top of page 205).

13. Claims 1, 4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshino et al. (US 5,250,549).

Yoshino et al. teach a compound having the claimed formula I and pharmaceutically acceptable salts of them (see entire disclosure, in particular column 1, line 5 to column 3, line 5 and compound 66 in example 28).

14. Claims 1-4, 6, and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleming et al. (US 7,238,717 B2) alone or in view of Elling et al. (US 2002/0061599 A1).

Fleming et al. teach a compound and pharmaceutical salts, solvates and hydrates having the claimed formula (I), wherein A is CO; D is COR₄; R₄ is a C₁ alkyl (methyl); each occurrence of X, Y, and Z are ring carbon atoms; R_{1a} and R_{1b} are H; R_{2a} is Cl; R_{3a} is H (see entire disclosure, in particular column 2, line 41 to column 3, line 10; column 4, lines 30-65 and compound 100 in column 29). Pharmaceutical compositions comprising compounds having the claimed formula I are also disclosed (see column 5, lines 59-61). The compounds are disclosed to be useful for the treatment of inflammatory diseases (see column 5, line 51 to column 6, line 9). Claims 14 and 15 are inherently taught by Fleming et al. since the compounds of Fleming et al. are taught to treat the same inflammatory diseases as the instant invention through a G-protein coupled receptor. Bradykinins and chemokines are G-protein coupled receptors (see paragraph 0077 of Elling et al.).

Allowable Subject Matter

15. Claims 5 and 7-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M, W & F 5:30-7:30 am & 1-5 pm; T & Th 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rosalynd Keys/
Primary Examiner
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August 1, 2007